SEP 0 8 2009

K091619

4. 510(k) Summary according to 807.92(c)

Contact: Mike Sinsheimer
AngleFix Tech, LLC.
1723 Beverly Drive
Charlotte, NC 28207
704-363-7532

Trade Name: AngleFix T Locking Plate

Product Class: Class II
Classification: 21 CFR §888.3030
Single/multiple component metallic bone fixation appliances and accessories
Product Codes: KTT
Panel Code: 87

Indications for Use: The AngleFix T Locking Plate is indicated for temporary stabilization of long bone fractures including:

- Proximal and distal fractures including joint fractures of the humerus, tibia and other long bones
- Metaphyseal, supracondylar, peri-articular, intra-articular, and intra-articular condylar fractures
- Diaphyseal fractures
- Ankle fractures
- Simple, comminuted and depression fractures
- Non-unions and malunions
- Osteotomies and bone reconstruction
- Fractures in normal or osteoporotic bone

Device Description: The AngleFix T Locking Plate consists of plates to accommodate the patients' anatomy. Each plate has threaded holes and "finger holes" for the corresponding screws.

Predicate Device(s): Howmedica VariAx Locking plate System (K060613), the Synthes 3.5mm LCP Distal Humerus System (K033995) and the Synthes AxSOS Plus Locking Plate System (K061012).

Performance Testing: The pre-clinical testing performed indicated that the AngleFix T Locking Plate is substantially equivalent to the predicate devices and is adequate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 0 8 2009

AngleFix Tech, LLC
% Silver Pine Consulting
Mr. Richard Jansen, Pharm D.
135 Guild Avenue
Apple Valley, Minnesota 55124

Re: K091619
Trade/Device Name: AngleFix T Locking Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: May 31, 2009
Received: June 10, 2009

Dear Mr. Jansen

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bucheld
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement of Indications for Use

510(k) Number (if known): K091619

Indications for Use:

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- Fractures in normal or osteoporotic bone

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janette J for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091619